IN THE UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF TEXAS
MARSHALL DIVISION

SEAGEN INC., *Plaintiff,* v. DAIICHI SANKYO CO., LTD., *Defendant,* ASTRAZENECA PHARMACEUTICALS LP, and ASTRAZENECA UK LTD, *Intervenor-Defendants.*	Civil Action No. 2:20-CV-00337-JRG

SEAGEN'S OPPOSITION TO DEFENDANTS' MOTION FOR JUDGMENT OF INVALIDITY BASED ON POST-TRIAL DISCLAIMER

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I. INTRODUCTION

Defendants' "motion for judgment" contends that Seagen's disclaimer of unasserted claims 6-8 invalidates the claims Seagen asserted at trial. Defendants' motion should be denied for at least three independent reasons: (1) it is procedurally improper, (2) Defendants' arguments fail as a matter of law because Seagen's disclaimer does not invalidate the asserted claims and the Patent Trial and Appeal Board's decisions have no issue preclusive effect, and (3) even if issue preclusion could apply, Defendants have not shown as a factual matter that the differences between the asserted claims and the disclaimed claims do not materially alter the question of invalidity.

Defendants' motion fails at the outset because it does not identify any rule that provides for the relief it seeks. But even if the motion were procedurally proper, it would still fail as nothing in the Patent Act, the Patent Office's regulations, or any case law supports Defendants' theory. Under the disclaimer statute and cases interpreting it, disclaimer affects only the disclaimed claims—not other claims in the patent. The Court should reject Defendants' attempt to reject existing precedent and invent a contrary rule by cobbling together cases interpreting a long-defunct version of the Patent Act or not even addressing disclaimer.

Equally flawed are Defendants' arguments based on the Board's adverse judgment on claims 6-8 in the PGR. Under the Board's estoppel regulation, the adverse judgment affects only actions taken by the patent owner in the Patent Office—not district court litigation—and there is nothing inconsistent about asserting claims different from those disclaimed anyway. And because the Board did not finally decide any patentability issues and can enter an adverse judgment for reasons unrelated to patentability, none of the requirements of issue preclusion could be satisfied.

As a backup, Defendants urge the Court to create another new rule for disclaimer—that disclaimed claims surrender the scope of non-disclaimed claims. Beyond being little more than a repackaging of their invalidity arguments, binding precedent rejects the very same claim-scope argument Defendants assert here.

II. PROCEDURAL HISTORY

Defendants filed two PGR petitions: one challenging claims 1-5, 9 and 10; the other challenging claims 6-8. In June 2021, the Patent Trial and Appeal Board (the "Board") denied institution of both PGRs under *Apple Inc. v. Fintiv, Inc.*, No. IPR2020-00019, Paper 11 at 5-6 (P.T.A.B. Mar. 20, 2020) (precedential), because the same issues in the PGRs would be presented to a jury in this Court at a trial set to take place months before the projected date for the Board to issue a decision in the PGRs.

Defendants filed requests for rehearing of the institution decisions, arguing that claims 6-8 had been dropped from this litigation, so there was no longer an "overlap" of claims for one of the PGRs, and the other PGR was substantively similar enough that the Board ought to institute it also. The requests for rehearing remained pending for eight months until April 2022, in the middle of the trial before this Court. At that point the Board granted rehearing "in light of the changed circumstances of claims 6–8 of the '039 patent no longer being asserted in the parallel district court proceeding." The Board found it appropriate in light of this changed circumstance to institute both PGR proceedings.

After trial was complete and the jury found the asserted claims to be valid and willfully infringed, Seagen filed a disclaimer with the United States Patent and Trademark Office, disclaiming claims 6-8, the only claims not adjudicated in the jury trial. Seagen then filed a request for rehearing with the Board, arguing that there were two changed circumstances that merited revisiting the institution decision: (1) claims 6-8, the Board's justification for its

rehearing decision to institute the PGRs, were no longer at issue before the PTAB, as Seagen had disclaimed those claims; and (2) there now was a jury verdict rejecting the very invalidity defenses Defendants hoped to present to the PTAB.

The Board agreed with Seagen. It found both changed circumstances justified reverting to its original decision to deny institution. As a result, it issued a decision granting rehearing and denying institution of the PGR challenging the asserted claims. The Board found that "[c]ontinuing with [the PGR] proceeding would result in duplicative efforts and potentially conflicting results between the district court and the Board." Decision Denying Institution at 7, *Daiichi Sankyo, Inc v. Seagen Inc.*, No. PGR2021-00030, Paper 31 (July 15, 2022).

III. THE MOTION FOR "JUDGMENT" IS PROCEDURALLY IMPROPER

As a threshold matter, Defendants' motion fails as it seeks "judgment" but fails to identify a basis for the motion under any Federal Rule of Civil Procedure. It is up to Defendants to identify a basis for their motion. Neither Seagen nor the Court should be required to guess which rule might justify the relief sought.

If the Court were inclined to search for an applicable rule, the motion would still fail. The motion could not have been brought under Rule 12 because pleading motions cannot be brought after the entry of judgment. *See, e.g.*, *EMG Tech., LLC v. Dr. Pepper Snapple Grp., Inc.*, No. 6:10-CV-536, 2012 U.S. Dist. LEXIS 205421, at *5 (E.D. Tex. Sept. 20, 2012) ("[a] motion for judgment on the pleadings provides a court with a method for summary adjudication of a defense after the pleadings are closed but *before trial*" (emphasis added)). Defendants could not have brought a post-trial motion for judgment as a matter of law under Rule 50(b) as it is not a "renewed" motion for an issue raised during the trial. Fed. R. Civ. P. 50(b) (permitting only "renewed" motions for issues timely raised in a Rule 50(a) motion made during trial). Defendants similarly could not have supported a motion to "amend or alter the judgment" under

Rule 59(e). *Imperium IP Holdings (Cayman), Ltd. v. Samsung Elecs. Co.*, C.A. No. 4:14-CV-00371, 2017 U.S. Dist. LEXIS 63979, at *7 (E.D. Tex. Apr. 27, 2017) (evidence that "was not in existence at the time of the judgment" cannot be "newly discovered evidence" under 59(e)). Defendants have also failed to make a showing of exceptional or extraordinary circumstances to justify relief from judgment under Rule 60. *See, e.g.*, *Imperium IP Holdings*, 2017 U.S. Dist. LEXIS 63979, at *6 n.1 (relief from judgment under Rule 60 requires "extraordinary circumstances"). In short, the Court should deny this motion as failing to support any claim to relief under an applicable rule of civil procedure.

IV. SEAGEN'S DISCLAIMER OF CLAIMS 6-8 HAS NO BEARING ON THE VALIDITY OF CLAIMS 1-5 AND 9-10

Even if Defendants had brought a procedurally proper motion, it would still fail. Defendants contend that the disclaimer of certain patent claims renders invalid other, non-disclaimed claims. (*See* Dkt. 442 at 10.) Yet Defendants cite no statute, regulation, or decision that so holds. Instead, Defendants stitch together snippets from decisions discussing pre-1952 patent law or cases having nothing to do with disclaimer. The Court should reject Defendants' invitation to manufacture new law.

A. Seagen's Disclaimer Cannot Invalidate Non-Disclaimed Claims

Neither the Patent Act nor precedent from any court supports Defendants' argument that disclaimer "invalidates claims that are not patentably distinct." (Dkt. 442 at 10.) For starters, the Patent Act says nothing about invalidating non-disclaimed claims. It merely states:

> Whenever a claim of a patent is invalid the remaining claims shall not thereby be rendered invalid. A patentee, whether of the whole or any sectional interest therein, may, on payment of the fee required by law, make disclaimer of any complete claim, stating therein the extent of his interest in such patent. Such disclaimer shall be in writing, and recorded in the Patent and Trademark Office; and it shall thereafter be considered as part of the original patent to the extent of the interest possessed by the disclaimant and by those claiming under him.

35 U.S.C. § 253(a). This text nowhere suggests that disclaimer of certain claims results in the

disclaimer or invalidation of any other patent claims. Rather, it expressly states that the invalidity of one claim does not make the other claims invalid and gives the patent owner the right to disclaim "any complete claim."

Consistent with this text, courts have acknowledged that disclaimer does not affect non-disclaimed claims. The Federal Circuit has explained that "disclaimer extends only to the particular claims involved and does not affect any other claims." *Magdo v. Kooi*, 699 F.2d 1325, 1329 (Fed. Cir. 1983). For that reason, "[n]othing in § 253 suggests that the disclaimer of a patent claim, by itself, has an effect on any other patent claim." *Anchor Wall Sys., Inc. v. Rockwood Retaining Walls, Inc.*, No. 99-1356 (JRT/FLN), 2007 WL 3237622, at *2 (D. Minn. Oct. 30, 2007). Anything less would violate the Federal Circuit rule that "each claim must be considered as defining a separate invention." *Jones v. Hardy*, 727 F.2d 1524, 1528 (Fed. Cir. 1984); *see* 35 U.S.C. § 282(a) ("Each claim of a patent (whether in independent, dependent, or multiple dependent form) shall be presumed valid independently of the validity of other claims.").

Nor does disclaimer even "invalidate" the disclaimed claims, as Defendants suggest. Disclaimer merely leaves the patent "as if the disclaimed claims had never existed." *Sanofi-Aventis U.S., LLC v. Dr. Reddy's Lab'ys, Inc.*, 933 F.3d 1367, 1373 (Fed. Cir. 2019); *see Vectra Fitness, Inc. v. TNWK Corp.*, 162 F.3d 1379, 1383 (Fed. Cir. 1998) (statutory disclaimer "effectively eliminate[s]" the disclaimed claims from the patent).

Unable to point to anything in the *present-day* Patent Act or cases construing current law, Defendants cobble together bits and pieces of old law to divine a purported patent law "core principle" that "disclaimer invalidates other claims that are not patentably distinct inventions." (Dkt. 442 at 9.) Their primary basis for that argument is the Supreme Court's decision in *Maytag Co. v. Hurley Machine Co.*, 307 U.S. 243 (1939). But *Maytag* created no such core

principle—it is one entirely of Defendants' invention. *Maytag* addressed the then-existing duty to promptly disclaim claims previously found invalid. Under the pre-1952 Patent Act, a patentee could not maintain an infringement action unless the remaining claims were "*definitely distinguishable* from the parts claimed without right"—that is, the claims previously found invalid. 35 U.S.C. § 71 (1946) (emphasis added).

In *Maytag*, claim 38 of the asserted patent had been held invalid in a prior proceeding. 307 U.S. at 244. The patentee disclaimed claims 1 and 38 but not claim 39, which recited a method similar to claim 38. *Id.* The patentee then sued a different defendant for infringement of other claims of the patent, not including claim 39. *Id.* at 244-45. The Supreme Court concluded that "claim 39 describes the same method as" claim 38, as they "describe[] no difference in operation or result" despite a "difference in verbiage." *Id.* at 246-47. And it explained that an entire patent becomes unenforceable when the patentee fails to disclaim claims that are not definitely distinguishable from already invalid claims. *Id.* Contrary to Defendants' assertion, the Supreme Court did not hold that "the patentee's disclaimer of Claim 38 resulted in the invalidation of undisclaimed method Claim 39 because it was not a distinct invention." (Dkt. 442 at 8.) It was the invalidation of claim 38 in a prior proceeding and the statutory bar against bringing suit based on claims not "definitely distinguishable from parts claimed without right," which rendered claim 39 unenforceable—not the patentee's disclaimer of claim 38.

Regardless, all the law on which *Maytag* was based no longer exists. As the Federal Circuit has recognized, "the *Maytag* rule did not survive the 'repeal' in the 1952 Patent Act of the provisions of the earlier Patent Act upon which *Maytag* rested." *Allen Archery, Inc. v. Browning Mfg. Co.*, 819 F.2d 1087, 1095 (Fed. Cir. 1987). Faced with this precedent, Defendants argue that *Maytag*'s "holding" had two "parts": (1) "the patentee's disclaimer of Claim 38 resulted in the invalidation of undisclaimed method Claim 39," and (2) "the entire

patent," including "otherwise valid" claims, were "invalid." (Dkt. 442 at 8.) According to Defendants, only "[t]he latter part of the Supreme Court's holding" is "no longer the law" after the 1952 Patent Act. (*Id.*) But as just discussed, *Maytag* created no core principle that "disclaimer invalidates other claims that are not patentably distinct inventions." (*Contra id.* at 9.) So Defendants' made-up principle could not survive the repeal in the 1952 Patent Act because it never existed.

In any event, Congress's repeal of the law on which *Maytag* relied was not so narrow. *Maytag* applied pre-1952 Patent Act's "provision that failure to disclaim additional invalid claims made the remaining valid claims unenforceable." *Allen Archery*, 819 F.2d at 1095-96 (noting that *Maytag* "rested upon the Court's interpretation of sections 65 and 71 of title 35 . . . as they then read"). In the 1952 Patent Act, Congress replaced that provision with Section 288, which specifies that when "a claim of a patent is invalid, an action may be maintained for the infringement of a claim of the patent which may be valid." 35 U.S.C. § 288. And Congress eliminated any reference to claims "definitely distinguishable" from invalid claims. Thus, nothing of *Maytag* survived the enactment of the 1952 Patent Act, as it "was expressly based on the statutory language that Congress deleted in 1952." *Allen Archery*, 819 F.2d at 1096.

Defendants' other pre-1952 Patent Act authority fares no better. (*See* Dkt. 442 at 7-11.) *Altoona Publix Theatres, Inc. v. Am. Tri-Ergon Corp.*, 294 U.S. 477 (1935), addressed pre-1952 Patent Act authority where patentees could disclaim part of a claim in addition to whole claims. *See* 35 U.S.C. § 65 (1934). In *Altoona*, the patentee had improperly used disclaimer to add "a new element to the combination previously claimed." 294 U.S. at 490. The Supreme Court held that the patentee could not "revive[]" the pre-disclaimer claims because the disclaimer "withdr[e]w" the original claims "from the protection of the patent laws"; nowhere did it hold that disclaimer of certain claims affected other, non-disclaimed claims of the patent. *Id.* at 492.

Nor do any of the post-1952 Patent Act cases Defendants cite address—or even suggest—that disclaimer affects non-disclaimed claims. In *Lemaire Illumination Technologies, LLC v. HTC Corp.*, C.A. No. 2:18-CV-00021-JRG, 2019 WL 1489065 (E.D. Tex. Apr. 4, 2019), for instance, this Court *declined* to enter partial judgment on the pleadings for the defendant after the patentee disclaimed certain asserted claims. *Id.* at *3. Instead, it "dismiss[ed]" the relevant infringement claims "without prejudice as moot" and observing that the dismissal "should not give rise to any form of claim preclusion." *Id.* at *3. And in *Guinn v. Kopf*, 96 F.3d 1419 (Fed. Cir. 1996), the "single issue" the Federal Circuit decided was "whether the Commissioner [of Patent and Trademarks] properly promulgated" a rule permitting the Board to construe a statutory disclaimer as a request for entry of an adverse judgment in an interference. *Id.* at 1421. The Federal Circuit held that the disclaimer did not deprive the Board of jurisdiction over the interference and that the rule did not improperly limit "the right of a patentee to statutorily disclaim subject matter" under 35 U.S.C. § 253. *Id.* at 1421-22.

The Court should reject Defendants' effort to extend old, repealed law so that the "disclaimer of [a claim] invalidates all claims of [the] patent that are patentably indistinct" from the disclaimed claim. (Dkt. 442 at 11.) *See Choon's Design, LLC v. Zenacon, LLC*, No. 2:13-CV-13568, 2015 WL 539441, at *6 (E.D. Mich. Feb. 9, 2015) (where defendants raised similar argument based on disclaimer of non-asserted claims during IPR, noting that "[t]his type of argument . . . is not found in the case law").

B. The Patent Office's Adverse Judgment Does Not Invalidate Any Non-Disclaimed Claims

The Patent Office's adverse judgment in the PGR on claims 6-8 based on Seagen's disclaimer of those claims provides no "independent basis" to invalidate claims 1-5 and 9-10. (*Contra* Dkt. 442 at 12.)

1. The Patent Office's Estoppel Regulation Does Not Render Seagen's Asserted Claims Invalid

a. Rule 42.73(d)(3) does not estop the patent owner in district court litigation

Contrary to Defendants' argument, the Board's estoppel regulation has no effect in this district court litigation because it governs only proceedings before the Patent Office. *Clearlamp, LLC v. LKQ Corp.*, No. 12 C 2533, 2016 WL 4734389, at *6 n.8 (N.D. Ill. Mar. 18, 2016) (rejecting defendant's argument that Board decision had preclusive effect in district court litigation under 37 C.F.R. § 42.73(d)(3)). This conclusion follows directly from the regulatory text and structure. Each of the three subsections of § 42.73(d) expressly apply only in the Patent Office or to actions that can occur only in the Patent Office. Both subsections (d)(1) and (d)(2) limit estoppel to "in the Office." 37 C.F.R. § 42.73(d)(1) ("A petitioner . . . is estopped *in the Office* from requesting or maintaining a proceeding with respect to a claim for which it has obtained a final written decision on patentability in an" AIA proceeding (emphasis added)); *id.* § 42.73(d)(2) ("In a derivation, the losing party who could have properly moved for relief on an issue, but did not so move, may not take action *in the Office* after the judgment that is inconsistent with that party's failure to move . . . ." (emphasis added)). And in subsection (d)(3), the only "action[s] inconsistent with the adverse judgment" the regulation discusses are ones a patent owner or applicant can do in the Office, such as "obtaining in any patent" certain claims or changes to a specification. 37 C.F.R. § 42.73(d)(3).

The Patent Office itself shares this understanding of the regulation's scope. In promulgating § 42.73(d)(3), the Patent Office explained that the regulation was "consistent with" the AIA provisions authorizing it to "prescribe regulations establishing and governing the reviews and the relationship of such reviews to *other proceedings under title 35*"—i.e., "proceedings" before the Office. *Rules of Practice for Trials Before the Patent Trial and Appeal*

Board and Judicial Review of Patent Trial and Appeal Board Decisions, 77 Fed. Reg. 48,612, 48,625 (Aug. 14, 2012) (emphasis added). The agency further described the effect of the "patent owner estoppel provisions" with reference only to Patent Office proceedings:

"Section 42.73(d)(3)(i), as adopted in this final rule, merely provides estoppel against claims that are patentably indistinct from those claims that were lost . . . during a trial," but permits the patent owner to "*present in a continuing or reissue application* claims that are patentably distinct from such claims." *Id.* at 48,649 (emphasis added). And at least one Board decision has recognized that § 42.73(d)(3)(i)'s estoppel effect "is limited to proceedings before the Office" and does not apply "in an infringement action." *Apple Inc. v. Softview LLC*, No. 2021-005530, 2022 WL 1210851, at *17 n.7 (P.T.A.B. Apr. 6, 2022).

The Patent Office's interpretation of its own regulation makes sense, because the only authority cited in promulgating § 42.73 were 35 U.S.C. §§ 316(a)(4) and 326(a)(4). *Rules of Practice*, 77 Fed. Reg. at 48,625. Those statutory provisions authorize the Patent Office to promulgate regulations governing only proceedings before the Patent Office. 35 U.S.C. § 316(a)(4) (inter partes reviews); *id.* § 326(a)(4) (same for post-grant reviews). Nowhere do they authorize the Patent Office to regulate outside of Patent Office proceedings, such as in district court litigation.

b. Seagen's assertion of the remaining claims is not inconsistent with the adverse judgment on the disclaimed claims

DSC's argument fails for yet another reason: Seagen's assertion of claims 1-5 and 9-10 is not an "action inconsistent with the adverse judgment" on claims 6-8. 37 C.F.R. § 42.73(d)(3). The text of § 42.73(d)(3) provides no support for Defendants' contention that an adverse judgment bars a patentee from asserting "patentably indistinct claims." (Dkt. 442 at 13.) The regulation uses "patentably distinct" only with reference to "a finally refused or cancelled claim," and only in the context of "obtaining" a patent. 37 C.F.R. § 42.73(d)(3). Defendants

point to nothing in the regulation's terms that could justify extending the bar on "not patentably distinct" claims to *disclaimed* claims and to *asserting* a patent.

Nor could they. After all, there is nothing "inconsistent" between disclaiming claims and continuing to assert other claims from the same patent. 37 C.F.R. § 42.73(d)(3). A statutory disclaimer just "effectively eliminate[s]" the disclaimed claim "from the original patent." *Vectra*, 162 F.3d at 1383. As the Federal Circuit has long recognized, a disclaimer does not concede the disclaimed claim's invalidity. *See Kloster Speedsteel AB v. Crucible Inc.*, No. 85-2174, 1986 WL 721181, at *12 (Fed. Cir. June 11, 1986) (rejecting defendant's argument that disclaimer of independent claim rendered invalid dependent claim as "based on conjecture respecting [patentee's] reasons for the disclaimer (i.e., that [patentee] recognized invalidity of those claims"); *cf. Motionless Keyboard Co. v. Microsoft Corp.*, 486 F.3d 1376, 1385 (Fed. Cir. 2007) ("A terminal disclaimer" under 35 U.S.C. § 253(b) "simply is not an admission that a later-filed invention is obvious."). For that reason, the regulation distinguishes between the separate bases of a "disclaimer of a claim such that the party has no remaining claim in the trial," 37 C.F.R. § 42.73(b)(2), and a "[c]oncession of unpatentability," *id.* § 42.73(b)(3).

Here, the adverse judgment entered in PGR2021-00042 after Seagen disclaimed claims 6-8 was simply a recognition that the patentee "has no remaining claim in the trial" before Board. 37 C.F.R. § 42.73(b)(2); *see* Judgment at 3, *Daiichi Sankyo, Inc. v. Seagen Inc.*, No. PGR2021-00042, Paper 25 (July 25, 2022) (granting Seagen's "request for adverse judgment pursuant to 37 C.F.R. § 42.73(b)(2)"). It was neither a concession by Seagen nor a determination by the Patent Office that claims 6-8 were unpatentable—much less that claims 1-5 and 9-10 were also unpatentable. There is thus no inconsistency between the adverse judgment and Seagen's

continued assertion of other claims not at issue in that proceeding.[1]

2. Issue Preclusion Does Not Invalidate Seagen's Asserted Claims

Defendants' issue preclusion arguments also fail. (Dkt. 442 at 10-11, 13-15.) Nothing in PGR2021-00042 finally adjudicated any validity or related issues as to claims 6-8. The proceeding merely ended because Seagen had disclaimed the challenged claims, leaving no live patentability challenge for the agency to decide. The "adverse judgment" thus can have no preclusive effect on any other claims.[2]

a. The validity of Seagen's claims was not actually litigated in the PGR and was not necessary to the final judgment

For issue preclusion, "[w]hen an issue of fact or law is actually litigated and determined by a valid and final judgment, and the determination is essential to the judgment, the determination is conclusive in a subsequent action between the parties." *B&B Hardware, Inc. v.*

[1] Defendants quote 37 C.F.R. § 42.73(a) but do not make any argument based on it. (*See* Dkt. 442 at 12.) For good reason. Under that provision, "[a] judgment, except in the case of a termination, disposes of all issues that were, or by motion reasonably could have been, raised and decided." 37 C.F.R. § 42.73(a). Rule 42.73(a) relates to "the effect of a judgment on a proceeding, but does not address future proceedings beyond that expressly set forth in Rule 42.73(d)." *VMware, Inc. v. Clouding Corp.*, No. IPR2014-01292, 2015 WL 10381774, at *3 (P.T.A.B. Dec. 3, 2015). In other words, that provision specifies that a judgment "disposes of" (and thus prohibits a party from raising in the same proceeding) an issue that "reasonably could have been[] raised" earlier; it has no bearing on a judgment's preclusive effect in other proceedings. *See id.*

[2] Defendants cite *SimpleAir, Inc. v. Google LLC*, 884 F.3d 1160 (Fed. Cir. 2018), which involved claim preclusion, but Defendants do not (and could not) invoke claim preclusion. (*See* Dkt. 442 at 11, 13.) "Under the doctrine of claim preclusion, a judgment on the merits in a prior suit involving the same parties or their privies bars a second suit based on the same cause of action." *SimpleAir*, 884 F.3d at 1165 (internal quotation marks omitted). The adverse judgment in the PGR based on Seagen's disclaimer of claims 6-8 was not "on the merits" of Defendants' patentability challenges. *See infra* p. 14. Regardless, *SimpleAir* involved infringement claims in successive district court actions. 884 F.3d at 1163. Defendants cite no authority suggesting that their request in the PGR for "agency reconsideration of a prior patent grant," *Regents of the Univ. of Minn. v. LSI Corp.*, 926 F.3d 1327, 1338 (Fed. Cir. 2019), involved the same cause of action as Seagen's claims that Defendants infringed its patents.

Hargis Indus., Inc., 575 U.S. 138, 148 (2015); *see SynQor, Inc v. Vicor Corp.*, 988 F.3d 1341, 1353 (Fed. Cir. 2021) ("Issue preclusion is appropriate only if . . . "the issue was actually litigated in the first action" and "resolution of the issue was essential to a final judgment in the first action," among other requirements). Neither the Board's institution decision nor the adverse judgment in the PGR on claims 6-8 satisfies the requirements for issue preclusion. *See Lucky Brand Dungarees, Inc. v. Marcel Fashions Grp., Inc.*, 140 S. Ct. 1589, 1595 (2020) (rejecting theory of preclusion that did not "satisfy the strictures of issue preclusion or claim preclusion").[3]

According to Defendants, "[t]he issue of the validity of Claim 8, including [its] entitlement to Seagen's asserted priority date, was actually litigated and resulted in institution of trial in PGR2021-00042." (Dkt. 442 at 15.) But the Board's institution decision in PGR2021-00042 did not *finally* resolve any invalidity issues. It merely determined that Defendants had "made a threshold showing that the claimed subject matter is not enabled for the full scope as claimed." Institution Decision at 27, *Daiichi Sankyo, Inc. v. Seagen Inc.*, No. PGR2021-00042, Paper 18 (Apr. 7, 2022); *see also, e.g., id.* at 37 ("preliminarily agree[ing]" with Defendants that claims 6-8 lacked written-description support). The Board stated that its "findings and conclusions" were "based on a preliminary record" and that it would "make a final determination on the patentability of the challenged claims, as necessary and applying the preponderance of the evidence standard, based on a fully developed record through trial." *Id.* at 42; *see Trivascular, Inc. v. Samuels*, 812 F.3d 1056, 1068 (Fed. Cir. 2016) (explaining that at institution, "the Board is considering the matter preliminarily without the benefit of a full record" and remains "free to change its view of the merits after further development of the record"). Given the preliminary

[3] Notably, Defendants do not contend that the Board's institution decision in PGR2021-00030, on asserted claims 1-5 and 9-10, has any preclusive effect in this litigation. (*See* Dkt. 442 at 5-15.)

nature of the institution decision, it stated no "conclusive" holdings that could give rise to issue preclusion. *B&B Hardware*, 575 U.S. at 147.

Nor does the Board's adverse judgment after institution have issue-preclusive effect. The patentability of claims 6-8 was neither "actually litigated" in the PGR nor was it "necessary to" the Board's adverse judgment. *Id.* at 148. After the Board instituted the PGR, Seagen disclaimed claims 6-8 and requested an adverse judgment based solely on the disclaimer. Request for Adverse Judgment at 1, *Daiichi Sankyo, Inc. v. Seagen Inc.*, No. PGR2021-00042, Paper 24 (May 11, 2022). The Board "determine[d] that entry of judgment against [Seagen] is appropriate" solely because Seagen's "disclaimer of claims 6-8 leaves no claims remaining in the trial." Judgment at 3, *Daiichi Sankyo, Inc. v. Seagen Inc.*, No. PGR2021-00042, Paper 25 (July 25, 2022). In entering that adverse judgment, the Board did not even opine on, let alone finally decide, the patentability of claims 6-8. The Board's adverse judgment thus does not satisfy the requirements of issue preclusion. *See Arizona v. California*, 530 U.S. 392, 414 (2000) (explaining that "consent judgments" generally do not support issue preclusion because "none of the issues is actually litigated"); *Best Med. Int'l, Inc. v. Elekta Inc.*, --- F.4th ---, No. 2021-2099, 2022 WL 3693470, at *4 (Fed. Cir. Aug. 29, 2022) ("non-appealable issues and judgments are without preclusive effect").

Defendants also contend that the Board's preliminary enablement and written-description determinations at institution were "necessary to the Adverse Judgment that ultimately issued" because otherwise "the patent would not have been eligible for PGR had it been entitled to Seagen's priority date." (Dkt. 442 at 15.) But entry of an adverse judgment does not even require institution. The Federal Circuit has held that the Patent Office's regulations "permit[] the Board to enter an adverse judgment when a patent owner cancels all claims at issue after an IPR petition has been filed," "before an institution decision." *Arthrex, Inc. v. Smith & Nephew, Inc.*,

880 F.3d 1345, 1350 (Fed. Cir. 2018). This means the Board had authority to enter an adverse judgment based on Seagen's disclaimer without finding the '039 patent eligible for PGR, which makes the Board's tentative views not "essential to" the adverse judgment. *B&B Hardware*, 575 U.S. at 148.

Defendants fare no better with their argument based on "preclusion from administrative judgments that arises from the cancellation authority of the [Patent Office]." (Dkt. 442 at 13-14.) "[W]hen a claim is cancelled, the patentee loses any cause of action *based on that claim*," rendering "moot" any infringement allegations based on the disclaimed claim. *Fresenius USA, Inc. v. Baxter Int'l, Inc.*, 721 F.3d 1330, 1340 (Fed. Cir. 2013) (emphasis added). But as explained, a statutory disclaimer surrenders the patentee's rights in only the disclaimed claims, not in other claims of the patent. *See supra* pp. 4-8; *see Sanofi-Aventis*, 933 F.3d at 1373 (holding that patentee's "disclaimer of the disclaimed claims mooted any controversy *over them*" (emphasis added)). None of Defendants' authorities supports the notion that disclaimer "extinguish[es]" a patentee's cause of action based on "claims that are not patentably distinct from" the disclaimed claims. (Dkt. 442 at 14.) That is just a repackaging of Defendants' flawed arguments about the effect of disclaimer. Whether phrased in terms of invalidity or extinguishment, Defendants' contentions fail.

b. Issue preclusion could not apply here because claims 1-5 and 9-10 raise materially different validity issues from disclaimed claims 6-8

Issue preclusion cannot apply here for another reason. Issue preclusion would require a finding that "the differences between the unadjudicated patent claims and adjudicated patent claims do not materially alter the question of invalidity." *Ohio Willow Wood Co. v. Alps S., LLC*, 735 F.3d 1333, 1342 (Fed. Cir. 2013). Instead of trying to meet that standard, Defendants attempt to show that the claims DSC was found to infringe are not "patentably distinct" from the

disclaimed claims because they "would have been either anticipated or obvious in light of" the disclaimed claims. (Dkt. 442 at 15-16 (citing *Eli Lilly & Co. v. Barr Lab'ys, Inc.*, 251 F.3d 955, 967 (Fed. Cir. 2001)).) But that "patentably distinct" inquiry is appropriate in "an obviousness-type double patenting analysis," *Eli Lilly*, 251 F.3d at 968, not to issue preclusion.

Defendants point to no case applying the double-patenting "patentably distinct" standard in assessing preclusion, and it would make no sense to do so. A dependent claim would always "anticipate" the claim from which it depends: "By definition, an independent claim is broader than a claim that depends from it." *Littelfuse, Inc. v. Mersen USA EP Corp.*, 29 F.4th 1376, 1380 (Fed. Cir. 2022). Defendants' theory would thus mean that disclaimer of a dependent claim necessarily invalidates any claims from which it depends. (*See* Dkt. 442 at 17-18.) Yet Defendants cite no authority endorsing that remarkable proposition.

Further, "obviousness-type double patenting doctrine" is "justified by a very different rationale than" preclusion doctrines. *Choon's Design*, 2015 WL 539441, at *7-8 (expressing "doubts" that double-patenting standard "is the appropriate analysis to determine whether estoppel under 37 C.F.R. § 42.73(d)(3) applies"). The prohibition on double patenting "prevent[s] unjustified timewise extension of the right to exclude granted by a patent." *Eli Lilly*, 251 F.3d at 968. In contrast, issue preclusion "protects a party from having to litigate issues that have been fully and fairly tried in a previous action." *Ohio Willow Wood*, 735 F.3d at 1342. Defendants offer no reason why the obviousness-type double patenting standard of "patentable distinctness" has any application here.

Defendants present no evidence showing that the "the differences between the unadjudicated patent claims and adjudicated patent claims do not materially alter the question of invalidity." *Ohio Willow Wood*, 735 F.3d at 1342. Defendants' expert was not asked to evaluate that question; his opinions are limited to his views about whether certain of Seagen's claims are

"patentably distinct" from other claims. (Dkt. 442, Ex. A ¶¶ 9-12.) He offered his views based on his understanding that "Claim B is not patentably distinct from a Claim A if it is anticipated by, or obvious in light of Claim A." (*Id.* ¶ 10.) He was not asked to opine on whether the claims at issue in this case raise materially different validity issues from disclaimed claims 6-8.

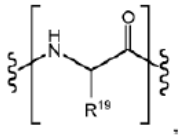
The evidence shows that the disclaimed claims *do* present issues that materially alter the question of patent validity. Claims 6 and 7 both include a requirement not present in any of the claims DSC was found to infringe: "wherein the bioavailability of the antibody-drug conjugate or an intracellular metabolite of the antibody-drug conjugate in a patient is improved" when compared to "a drug compound comprising the drug moiety" of the claimed ADC (claim 6) or when compared to "an analog of the antibody-drug conjugate not having the drug moiety" (claim 7).

Defendants' own contentions in this case confirm that claims 6 and 7 raise these distinct invalidity issues. During claim construction proceedings, Defendants contended that these claims were indefinite because they "[do] not provide reasonable certainty at least regarding (i) how the POSA would understand the scope of, including how to measure, 'the bioavailability of the antibody-drug conjugate or an intracellular metabolite of the antibody-drug conjugate in a patient is improved when compared to a drug compound comprising the drug moiety of the antibody-drug conjugate' and (ii) how the POSA would interpret the scope of 'bioavailability . . . is improved.'" (Dkt. 106-1, Joint Claim Construction Statement Ex. A at 8-9.) These indefiniteness issues—which apply only to claims 6 and 7—were never resolved as Seagen dropped claims 6 and 7 from the case before the claim construction hearing.

Claim 8 differs from the other claims by requiring that "the drug moiety is intracellularly cleaved in a patient from an intracellular metabolite of the antibody-drug conjugate." The other claims, by contrast, depend from claim 1 and specify an ADC "wherein the drug moiety is

intracellularly cleaved in a patient from the antibody of the antibody-drug conjugate or an intracellular metabolite of the antibody-drug conjugate." By covering ADCs that are intracellularly cleaved from either the ADC itself or a metabolite of the ADC, the claims other than claim 8 effectively cover *any* type of intracellular cleavage. Claim 8, by contrast, requires that the drug moiety is intracellularly cleaved specifically from an intracellular metabolite of the ADC. Claim 8 thus has very different scope from the other claims.

Again, Defendants' own contentions in this case show that claim 8 presents issues that materially affect validity. In their invalidity contentions, Defendants stated that the patent suffered from "[l]ack of [e]nablement for the following claim limitations," and then listed several limitations including "the drug moiety is intracellularly cleaved in a patient from an intracellular metabolite of the antibody-drug conjugate." (Invalidity Contentions at 6.) Defendants similarly asserted that the patent lacked written description support for a series of limitations, including "the drug moiety is intracellularly cleaved in a patient from an intracellular metabolite of the antibody-drug conjugate." (*Id*. at 6-7.) Defendants also included a chart outlining their contention that "the Asserted Patent does not enable the person of ordinary skill in the art to make or use the full scope of antibody-drug conjugates that meet, *inter alia*, the following claim limitations":

Claim(s)	'039 Patent Claim Limitation
1–10	"each —W_w— unit is a tetrapeptide, wherein each —W— unit is independently an Amino Acid unit having the formula denoted below in the square bracket:  wherein R^{19} is hydrogen or benzyl"
1–10	"D is a drug moiety"
1–7, 9, and 10	"the drug moiety is intracellularly cleaved in a patient from the antibody of the antibody-drug conjugate or an intracellular metabolite of the antibody-drug conjugate"
8	"the drug moiety is intracellularly cleaved in a patient from an intracellular metabolite of the antibody-drug conjugate"
1–3, 6–10	"p ranges from 1 to about 20"
1–10	"Y is a Spacer unit"

(*Id.* at 21.) As is apparent, Defendants themselves identified a separate validity issue for claim 8. Defendants included a similar chart for their contention that "the full scope of antibody-drug conjugates that meet, *inter alia*, the following claim limitations is not sufficiently described by the Asserted Patent." (*Id.* at 22-23.) Claim 8's "drug moiety is intracellularly cleaved in a patient from an intracellular metabolite of the antibody-drug conjugate" limitation is also separately identified as a purported basis for lack of written description.

V. SEAGEN'S DISCLAIMER DOES NOT ALTER THE SCOPE OF THE ASSERTED CLAIMS

In the alternative, Defendants argue that "Seagen's disclaimer had the effect of disavowing the scope of the asserted claims." (Dkt. 442 at 27.) According to Defendants, by

disclaiming claim 8, claim 1 no longer covers ADCs also covered by claim 8. (*Id.*)

Binding precedent that Defendants overlook forecloses their contention. In *Soundscriber Corp. v. United States*, 360 F.2d 954 (Ct. Cl. 1966), the accused infringer argued that the patentee was "estopped to charge infringement of" the asserted claim because the patentee had "disclaimed a claim in the [relevant] patent which is dependent upon" that asserted claim. *Id.* at 957. The Court of Claims (one of the Federal Circuit's two predecessor courts) rejected that argument as "without merit." *Id.* at 961.[4] It explained that "[t]he construction of a patent, after a disclaimer has been properly entered, must be the same that it would have been if the matter so disclaimed had never been claimed." *Id.* Thus, products covered "by a claim which has been disclaimed may be covered by other claims not disclaimed." *Id.*; *see also, e.g.*, *Ford Motor Co. v. Versata Software, Inc.*, No. 15-11624, 2017 WL 3485812, at *3 (E.D. Mich. Aug. 15, 2017) (relying on *Soundscriber* to conclude that "where a party disclaims a dependent claim, the subject-matter of that claim does *not* automatically revert to the public"). Again, "each claim must be considered as defining a separate invention." *Jones*, 727 F.2d at 1528. Seagen's disclaimer of the inventions covered by claims 6-8 has no bearing on the scope of the inventions covered in claim 1 and the other asserted claims.

Defendants' related arguments fail for the same reason. Defendants argue that Seagen "surrender[ed]" part of claim 1's scope by "disclaimer" of claim 8, and that Seagen's assertion of claim 1 in this litigation thus constitutes an improper attempt to "correct[]" a "defective patent[]" outside the reissue process and an effort to "retain or recapture surrendered claims." (Dkt. 442 at

[4] The Federal Circuit has "adopted as precedent the decisions of the U.S. Court of Claims." *Ginsburg v. United States*, 922 F.3d 1320, 1325 n.4 (Fed. Cir. 2019) (citing *S. Corp. v. United States*, 690 F.2d 1368, 1369 (Fed. Cir. 1982) (en banc)); *see, e.g.*, *CoreBrace LLC v. Star Seismic LLC*, 566 F.3d 1069, 1073 (Fed. Cir. 2009) (citing Court of Claims decision as "bind[ing]" precedent in patent case).

28-29.) But as explained, Seagen's disclaimer of claim 8 is not a concession that the subject matter recited in that claim is unpatentable, nor does the disclaimer of claim 8 affected the scope of claim 1. *See supra* pp. 11, 19-20. The disclaimer of claims 6-8 merely "leav[es] the ['039] patent as if the disclaimed claims had never existed"; it has no effect on the non-disclaimed claims. *Sanofi-Aventis*, 933 F.3d at 1373.

Defendants' cited cases do not hold otherwise. (*See* Dkt. 442 at 11, 29.) *Glaxo Wellcome, Inc. v. Impax Laboratories, Inc.*, 356 F.3d 1348 (Fed. Cir. 2004), involved prosecution history estoppel, not statutory disclaimer. *Id.* at 1351. The Federal Circuit noted that, in assessing infringement under the doctrine of equivalents, "subject matter surrendered via claim amendments during prosecution is also relinquished for other claims containing the same limitation." *Id.* at 1356. That rule prohibits a patentee from "recaptur[ing]" subject matter "surrendered" during prosecution "by asserting a claim that was not amended." *Id.* As explained, however, Seagen's disclaimer of claims 6-8—which depend from and are thus narrower than claims 1-5—did not surrender any claim scope. *See supra* pp. 19-20.

Similarly, *Gilead Sciences, Inc. v. Natco Pharma Ltd.*, 753 F.3d 1208 (Fed. Cir. 2014), involved obviousness-type double patenting, not disclaimer. *Id.* at 1214. The Federal Circuit noted that "when a patent expires, the public is free to use not only the same invention claimed in the expired patent but also obvious or patentably indistinct modifications of that invention." *Id.* But Defendants are wrong that "[t]he rule is no different when an invention enters the public domain by disclaimer." (Dkt. 442 at 11.) When a patent expires, the patentee "has already enjoyed rights" for the duration of the patent term; double-patenting doctrine precludes a patentee from obtaining an "unjustified timewise extension" of those exclusive rights. *Boehringer Ingelheim Int'l GmbH v. Barr Lab'ys, Inc.*, 592 F.3d 1340, 1348 (Fed. Cir. 2010). By contrast, a statutory disclaimer leaves the patent "as if the disclaimed claims had never

existed." *Sanofi-Aventis*, 933 F.3d at 1373.

VI. CONCLUSION

For these reasons, Defendants' Motion for Judgment of Invalidity Based on Post-Trial Disclaimer should be denied.

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that counsel of record who are deemed to have consented to electronic services are being served with a copy of this document via the Court's CM/ECF system per Local Rule CV-5(a)(3) on this the 22 day of September, 2022.

/s/ Melissa R. Smith